UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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NOVARTIS PHARMA AG,

Plaintiff,

-against-

AMGEN INC.,

Defendant.

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19-cv-2993 (PKC)

OPINION
AND ORDER

CASTEL, U.S.D.J.

This is a declaratory judgment action between two major pharmaceutical companies, plaintiff Novartis Pharma AG ("Novartis") and defendant Amgen Inc. ("Amgen"). The parties agreed to collaborate on a migraine-treatment drug called erenumab, which is sold and marketed under the brand name Aimovig. They entered into two agreements governing their collaboration. The first agreement, which was entered in August 2015, provided that Novartis would collaborate with Amgen in the development and commercialization of Aimovig in countries other than the United States, Canada and Japan (the "2015 Agreement"). The second agreement, which was entered in April 2017, provided that Novartis would collaborate with Amgen on Aimovig's commercialization in the United States (the "2017 Agreement"). When the parties entered into the 2017 Agreement, they also agreed to extensive amendments to the 2015 Agreement, with the intention of harmonizing it with the 2017 Agreement ("Amendment No. 2.").

Unbeknownst to Novartis and Amgen, in May 2015, non-party Sandoz GmbH ("Sandoz") entered into a Contract Manufacturing Agreement ("CMA") with non-party Alder Pharmaceuticals ("Alder") for the manufacture of a different migraine-treatment drug called

eptinezumab, or ALD403. Novartis and Sandoz share a common corporate parent, and in its submissions, Novartis refers to Sandoz as its "sister" company. Amgen has asserted that the Sandoz-Alder CMA violates the parties' agreement not to participate in a so-called "Distracting Program," and has sent notice to Novartis purporting to terminate the 2015 and 2017 Agreements.

Novartis's First Amended Complaint (the "Complaint") brings five claims for relief, including claims under the Declaratory Judgment Act seeking declarations that Novartis did not breach the agreements of 2015 or 2017 (Count I and Count II), and that any breach was timely cured (Count IV). Amgen has filed an Answer and Counterclaims. (Docket # 36.) Both parties have moved under Rule 12(c), Fed. R. Civ. P., for partial judgment on the pleadings in their favor. Novartis seeks judgment in its favor on its claim on Count II, which seeks a declaration that it did not breach the 2017 Agreement. (Docket # 44.) Amgen moves under Rule 12(c) to dismiss Counts I, II and IV brought by Novartis. (Docket # 52.)

The motions directed to Count II turns entirely on the language of the parties' agreements, which neither party asserts is ambiguous. For the reasons that will be explained, the Court concludes that the 2017 Agreement does not bar participation in a "Distracting Program." Novartis's motion for judgment in its favor on Count II is therefore granted, and Amgen's motion to dismiss that claim will be denied. As to Count I and Count IV, Amgen's motion will be denied because it requires consideration of facts that go beyond the pleadings.

BACKGROUND.

A. The Parties' Agreements on Aimovig's Development and Commercialization.

Prior to August 28, 2015, Amgen had exclusive ownership and control of all rights to Aimovig. (Compl't ¶ 15.) Amgen concluded that a business collaboration could help it

commercialize Aimovig in the global market, and, in August 2015, it entered into the 2015 Agreement with Novartis, under which Novartis obtained a right to commercialize Aimovig in markets other than the United States, Canada and Japan, in exchange for Novartis's investment in the drug's development. (Compl't ¶ 17; CC ¶¶ 6, 22-25.) As of the Complaint's filing, Aimovig had launched in 27 countries, with additional launches anticipated in 19 more. (Compl't ¶ 19.)

The parties' motions turn in substantial part on section 7.2 of the 2015 Agreement, in which each party agreed not to participate in a so-called "Distracting Program." Section 7.2 states that "neither Party shall, itself or through its Affiliates, directly or indirectly conduct or participate in, or advise, assist or enable a Third Party to conduct or participate in, any Distracting Program." The 2015 Agreement defines a "Distracting Program" to "mean[] the clinical development, commercialization or manufacture of any Distracting Product." (2015 Agrmt. § 1.37.) A "Distracting Product" is defined as "any compound or product, via any modality, that has the same primary intended mechanism of action as a Licensed Product (i.e., any inhibitor or modulator of CGRP, CGRP receptor, PACAP and/or PACAP receptor (excluding the Licensed Products and, in the case of Amgen only, Franchise Product 3, but including any Biosimilar Product))." (2015 Agrm't § 1.36.)

Amgen and Novartis entered into the 2017 Agreement on April 21, 2017, pursuant to which Novartis obtained co-commercialization rights for Aimovig in the United States. (Compl't ¶ 20; CC ¶¶ 7, 34, 41.) On that same date, the parties also executed Amendment No. 2 to the 2015 Agreement, which amended portions of the 2015 Agreement to harmonize its terms with the 2017 Agreement, and also expanded the 2015 Agreement to include the Canadian market. (Hille Dec. Ex. 3.) Novartis thereafter invested $530 million in Aimovig.

(Compl't ¶ 20.) According to the Complaint, Aimovig has exceeded commercial expectations, and has outsold competing products launched at around the same time. (Compl't ¶ 20.)

B. The Events Leading to Amgen' Notice of Termination.

In summer 2018, Novartis learned that, in 2015, Sandoz entered into the CMA with Alder for the manufacture of eptinezumab. (Compl't ¶ 23.) Sandoz is an indirect subsidiary of Sandoz Inc., which, in turn, shares a common corporate parent with Novartis. (Compl't ¶ 24.) Eptinezumab is being developed to treat migraines but has not been approved for sale. (Compl't ¶ 25.)

In September 2018, Novartis sent written notice to Amgen describing Sandoz's role in the manufacture of eptinezumab. (Compl't ¶ 27; CC ¶ 11.) As characterized by Novartis, it sent this notice "in good faith and in the interest of maintaining an open collaboration." (Compl't ¶ 27.)

On November 29, 2018, Amgen responded with a formal notice of material breach, which asserted that Novartis had breached both the 2015 and 2017 Agreements. (Compl't ¶ 28.) The breach notice asserted that eptinezumab fell within the definition of a "Distracting Product" as set forth in section 7.2 of the 2015 Agreement. (Compl't ¶ 36.)

In its Counterclaims, Amgen asserts that at the time that it entered into the 2015 and 2017 Agreements with Novartis, it had no knowledge that Sandoz had entered into the CMA with Alder. (CC ¶ 9.) The Counterclaims assert that Sandoz is involved in the commercialization of Aimovig, and that certain of Novartis's overseas regulatory filings identified Sandoz as the "marketing authorization holder" for Aimovig. (CC ¶¶ 8, 10, 49-51.) Amgen alleges that based on its chemical properties, Alder's eptinezumab product is a "Distracting Product," and that Sandoz has contributed to its development. (CC ¶¶ 52-63.)

Amgen alleges that Sandoz has agreed to continue supply Alder with eptinezumab until at least 2023. (CC ¶¶ 62, 65.)

The 2015 and 2017 Agreements contain identical protocols for noticing a material breach, and require a cure period and formal notice of termination. (Compl't ¶ 37.) On January 24, 2019, Novartis responded to Amgen's breach notice, disputed the existence of a material breach, and asserted that any breach had been cured. (Compl't ¶ 29; CC ¶¶ 73, 78.) Specifically, Novartis asserted that Sandoz and Alder had agreed to terminate the CMA, although Sandoz would continue to manufacture eptinezumab for another three to five years in order to facilitate a "complex technology transfer." (Compl't ¶¶ 56-57.) As described in the Counterclaims, Novartis also acknowledged that Sandoz was its "Affiliate" and that the Alder-Sandoz relationship began on May 4, 2015. (CC ¶¶ 74-75.)

On April 2, 2019, Amgen sent Novartis a notice of termination of the two agreements. (Compl't ¶ 30; CC ¶ 79.) On that same date, pursuant to the protocols set forth in the agreements, Novartis issued a "Notice of Disagreement in Good Faith." (Compl't ¶ 31.)

Novartis commenced this action on April 4, 2019. (Docket # 1.) It brings claims under the Declaratory Judgment Act and seeks declarations that it did not breach the 2015 or 2017 Agreements, or, alternatively, that any breach was not material and had been cured by Novartis. Amgen's counterclaims seek a declaration that Novartis materially breached the 2015 and 2017 Agreements, and also brings claims for breach of contract and negligent misrepresentation.

Discovery in this case is ongoing. Fact discovery is currently scheduled to close on August 10, 2020, with expert discovery to close on October 13, 2020. (Docket # 94.)

RULE 12(c) STANDARD.

Amgen moves to dismiss three claims brought by Novartis. Rule 12(c) states that "[a]fter the pleadings are closed – but early enough not to delay trial – a party may move for judgment on the pleadings." A motion to dismiss pursuant to Rule 12(c) is governed by the same standards as a motion to dismiss pursuant to Rule 12(b)(6), Fed. R. Civ. P. Eastman Kodak Co. v. Henry Bath LLC, 936 F.3d 86, 93 (2d Cir. 2019). On a motion to dismiss, the Court accepts the Complaint's factual allegations as true and draws all inferences in favor of the non-movant. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id.

Where a plaintiff moves for judgment in its favor based on the pleadings, the plaintiff "'impliedly admits the truth of its adversary's allegations and the falsity of its own assertions that have been denied by that adversary.'" Gioconda Law Grp. PLLC v. Kenzie, 941 F. Supp. 2d 424, 427 (S.D.N.Y. 2013) (Oetken, J.) (quoting 5C Charles Alan Wright & Arthur R. Miller, et al., Federal Practice and Procedure, § 1370 (3d ed. 1998)). Generally, "federal courts are 'unwilling to grant a motion under Rule 12(c) unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law.'" Id. (quoting Fed. Prac. & Proc. § 1368). However, judgment on the pleadings may be "particularly appropriate in a dispute regarding a breach of contract where the primary issue is determining the parties' legal rights and obligations." Neopharm Ltd. v. Wyeth–Ayerst Int'l LLC, 170 F. Supp. 3d 612, 615 (S.D.N.Y. 2016) (Stein, J.).

DISCUSSION.

I. Because the 2017 Agreement Does Not Include a "Distracting Program" Provision or Incorporate Section 7.2 of the 2015 Agreement, Novartis's Motion Is Granted as to Count II and Amgen's Motion Is Denied.

A. New York Law Governing Contract Interpretation.

Novartis asserts that the Sandoz-Alder CMA could not breach the 2017 Agreement because the 2017 Agreement does not include a "Distracting Program" provision or incorporate the relevant provision at section 7.2 of the 2015 Agreement. Amgen disagrees, and urges that the 2017 Agreement and Amendment No. 2 reflect the parties' intent to incorporate section 7.2 into the 2017 Agreement. The parties agree that the relevant contractual language is unambiguous, and they both seek judgment on the pleadings in their favor.

Both agreements contain a New York choice-of-law provision, and the parties agree that New York law governs their claims. (2015 Agrm't § 16.3; 2017 Agrm't § 15.3.) "In New York, agreements negotiated at arm's length by sophisticated, counseled parties are generally enforced according to their plain language pursuant to our strong public policy favoring freedom of contract." 159 MP Corp. v. Redbridge Bedford, LLC, 33 N.Y.3d 353, 356 (2019). "A reading of the contract should not render any portion meaningless. Further, a contract should be read as a whole, and every part will be interpreted with reference to the whole; and if possible it will be so interpreted as to give effect to its general purpose." Beal Sav. Bank v. Sommer, 8 N.Y.3d 318, 324-25 (2007). "Courts will give effect to the contract's language and the parties must live with the consequences of their agreement. If they are dissatisfied, the time to say so is at the bargaining table." Eujoy Realty Corp. v. Van Wagner Commc'ns, LLC, 22 N.Y.3d 413, 424 (2013) (quotation marks and alterations omitted). "[I]f parties to a contract omit terms – particularly, terms that are readily found in other, similar

contracts – the inescapable conclusion is that the parties intended the omission." Quadrant Structured Prod. Co. v. Vertin, 23 N.Y.3d 549, 560 (2014).

"In general, 'when two parties have made two separate contracts it is more likely that promises made in one are not conditional on performances required by the other.'" Novick v. AXA Network, LLC, 642 F.3d 304, 312 (2d Cir. 2011) (quoting Rudman v. Cowles Communications, Inc., 30 N.Y.2d 1, 13 (1972)). At the same time, "[w]here several instruments constitute part of the same transaction, they must be interpreted together." BWA Corp. v. Alltrans Express U.S.A., 112 A.D.2d 850, 852 (1st Dep't 1985). "In determining whether contracts are separable or entire, 'the primary standard is the intent manifested, viewed in the surrounding circumstances.'" Davimos v. Halle, 60 A.D.3d 576, 577 (1st Dep't 2009) (quoting Williams v. Mobil Oil Corp., 83 A.D.2d 434, 439 (2d Dep't 1981)).

B. The "Distracting Program" Provision of the 2015 Agreement.

Section 7.2 of the 2015 Agreement is headed "Activities Outside the Collaboration." It states in part that "during the Term, neither Party shall, itself or through its Affiliates, directly or indirectly, conduct or participate in, or advise, assist or enable a Third Party to conduct or participate in, any Distracting Program." (2015 Agrmt. § 7.2.) The agreement defines a "Distracting Program" as "the clinical development, commercialization or manufacture of any Distracting Product." (2015 Agrmt. § 1.37.) A "Distracting Product" is defined as "any compound or product, via any modality, that has the same primary intended mechanism of action as a Licensed Product (i.e., any inhibitor or modulator of CGRP, CGRP receptor, PACAP and/or PACAP receptor . . . ." (2015 Agrmt. § 1.36.)

Sections 7.3 and 7.4 of the 2015 Agreement separately set forth the parties' rights and obligations related to their participation in a "Distracting Transaction." A "Distracting

Transaction" is defined as a transaction wherein Novartis or Amgen become affiliated with a third party that is already engaged in a "Distracting Program." (2015 Agrmt. § 1.38.) Amgen does not claim that sections 7.3 or 7.4 were breached. As will be discussed, the 2017 Agreement refers to section 7.4, but does not reference section 7.2.

C. The Survivability Provision of Amendment No. 2.

In 2017, the parties amended the 2015 Agreement to harmonize its terms with the 2017 Agreement, as well as to expand the 2015 Agreement to provide for the parties' collaboration in Canada. Like the 2017 Agreement, Amendment No. 2 was executed on April 21, 2017. (Hille Dec. Ex. 3.)

Of relevance to this motion, Amendment No. 2 amended the 2015 Agreement to provide that the "Distracting Program" provision of section 7.2 would survive the termination of the 2015 Agreement, and remain in effect for as long as the 2017 Agreement was in effect. As originally drafted in the 2015 Agreement, section 7.2 would be in effect "during the Term . . . ." (2015 Agrmt. § 7.2.) Section 7.2 was not originally listed among the provisions that would survive termination of the 2015 Agreement. (2015 Agrmt. § 15.4.)

Amendment No. 2 deleted and replaced the survivability provision of the 2015 Agreement, and included the following language:

> [I]n the event of any expiration or termination of this [2015] Agreement the following provisions shall survive: . . . 7.2 (Activities Outside the Collaboration) through 7.4 (Termination or Divestiture) (inclusive) (solely in the event this [2015] Agreement expires or earlier terminates prior to the expiration or earlier termination of the [2017 Agreement], solely with respect to any Franchise Product 1 [Aimovig] Distracting Program and solely for the term of the [2017 Agreement]).

(Amendment No. 2 § 2.55; bracketed language added by the Court.) Thus, Amendment No. 2 amended the 2015 Agreement to provide that section 7.2 would survive the termination of the 2015 Agreement and remain in effect "solely for the term of the [2017 Agreement]." (Id.)

The survivability of sections 7.2 to 7.4 applied "solely with respect to any Franchise Product 1 Distracting Program . . . ." (Id.) "Franchise Product 1 Distracting Program" is defined in Amendment No. 2 as "the clinical development, commercialization or manufacture of any Franchise Product 1 Distracting Product." (Amendment No. 2 § 2.5.) "Franchise Product 1 Distracting Product" is defined as "any compound or product, via any modality, that has the same primary intended mechanism of action as Franchise Product 1 (i.e., any inhibitor or modulator of CGRP or CGRP receptor (excluding Franchise Product 1 and, in the case of Amgen only, Franchise Product 3, but including any Biosimilar Product))." (Id.) It is undisputed that Aimovig is a CGRP inhibitor. Thus, section 7.2 is to survive termination of the 2015 Agreement, but only as to a "Distracting Product" involving a CGRP inhibitor like Aimovig, and not a broader category of products, such as "any . . . PACAP and/or PACAP receptor . . . ." (2015 Agrmt. § 1.36; Amendment No. 2 §§ 2.5, 2.55.) According to Amgen, this narrower focus reflects the parties' common interest in commercializing Aimovig in the United States under the 2017 Agreement. (Amgen Mem. 9-10.)

D. The Text of the 2017 Agreement.

The recitals to the 2017 Agreement stated that the 2015 Agreement was simultaneously being amended to include Canada, and to "amend, modify and restate certain terms and conditions . . . in connection with this Agreement . . . ." (2017 Agrm't p. 1.) The 2017 Agreement adopted all defined terms set forth in the 2015 Agreement. (2017 Agrm't § 1.)

The 2017 Agreement does not include a "Distracting Program" provision similar to section 7.2 to the 2015 Agreement. It uses the term "Distracting Program(s)" twice.

First, section 14.2.7 of the 2017 Agreement is entitled "Termination for Distracting Program" and provides that "Amgen shall have the right to terminate this Agreement upon thirty (30) days' prior written notice to Novartis pursuant to Section 7.4 (Termination or Divesture) of the [2015] Agreement." As noted, sections 7.3 and 7.4 of the 2015 Agreement relate to the parties' rights and obligations as to any "Distracting Transaction," which is distinct from a "Distracting Program." Amgen has not contended that Novartis entered into a "Distracting Transaction," and Amgen does not rely on section 14.2.7 of the 2017 Agreement or sections 7.3 or 7.4 of the 2015 Agreement in asserting a breach by Novartis.

Second, section 10.3 of the 2017 Agreement uses the term "Distracting Programs" in its heading, and provides that the parties "shall not utilize" confidential information, except as otherwise agreed. Amgen also does not rely on this provision or claim that it has been breached.

The text of the 2017 Agreement does not otherwise refer to "Distracting Program(s)."

The 2017 Agreement's omission of a "Distracting Program" provision reflects the parties' intent not to incorporate such a provision in that agreement. "[I]f parties to a contract omit terms – particularly, terms that are readily found in other, similar contracts – the inescapable conclusion is that the parties intended the omission." Quadrant Structured Prod. Co., 23 N.Y.3d at 560; see also Bank of New York Mellon Tr. Co. v. Morgan Stanley Mortg. Capital, Inc., 821 F.3d 297, 306 (2d Cir. 2016) ("The failure to couch the request-for-cure provision in the explicit language of condition is particularly significant here because the sophisticated

drafters elsewhere employed precisely such language to establish undoubted conditions precedent.").

Nor does the 2017 Agreement incorporate by reference section 7.2 of the 2015 Agreement. If the parties had intended to incorporate section 7.2, they would have done so. The 2017 Agreement makes numerous references to the 2015 Agreement. By Novartis's count, there are 29 such references. (See, e.g., 2017 Agrm't §§ 2.5.2 (incorporating section 3.5 of the 2015 Agreement); 8.6.3 (incorporating section 9.7.3 of the 2015 Agreement); 8.9 (certain audit rights "shall be governed by section 9.11" of the 2015 Agreement).) Paragraph 47 of Amgen's counterclaims lists several sections of the 2015 Agreement incorporated in the 2017 Agreement. Moreover, as previously noted, the 2017 Agreement expressly incorporates the "Distracting Transaction" notice provision of section 7.4 of the 2015 Agreement while not incorporating the "Distracting Program" provision of section 7.2. (2017 Agrmt. § 14.2.7.)[1]

In opposition, Amgen points to the merger clause of the 2017 Agreement, which states that "[t]his Agreement . . . together with the [2015] Agreement, constitutes the entire agreement between the Parties as to the subject matter of this Agreement" and supersedes and merges any other negotiations or representations. (2017 Agrmt. § 15.6.) Typically, a merger clause "establish[es] the parties' intent that the Agreement is to be considered a completely integrated writing" and "precludes extrinsic proof to add to or vary its terms." Primex Int'l Corp.

[1] At first blush, it would appear that section 14.2.7 of the 2017 Agreement supports Amgen's position. The section reads in full: "Termination for Distracting Program. Amgen shall have the right to terminate this [2017] Agreement upon thirty (30) days' prior written notice to Novartis pursuant to Section 7.4 (Termination or Divestiture) of the [2015] Agreement." (Id.) However, Amgen does not urge that this provision authorizes it to terminate the 2017 Agreement based on Sandoz's manufacturing relationship with Alder. Amgen explains: "The 2017 Agreement's reference to Section 7.4 does not refer to termination as a remedy for certain kinds of breach—impliedly excluding it for other kinds—but to *Amgen's option* to terminate the collaboration if *Amgen* has a Distracting Transaction. Further, it is not surprising that the 2017 Agreement refers to Section 7.4 because it was amended in 2017 so that Amgen's Distracting Transaction termination option now depends on regulatory approval in the lucrative United States market, where Novartis co-commercializes [Aimovig] by virtue of the 2017 Agreement." (Opp. Mem. 22 at n. 97; emphasis in original.)

v. Wal-Mart Stores, Inc., 89 N.Y.2d 594, 599-600 (1997); see also Torres v. D'Alesso, 80 A.D.3d 46, 53 (1st Dep't 2010) ("Merger clauses are not mere boilerplate. They provide further protection for the interests of certainty and finality.") (emphasis in original). The contents of merger clauses vary, however, and may sometimes include language that expressly harmonizes or modifies prior agreements. See, e.g., iSentium, LLC v. Bloomberg Fin. L.P., 2020 WL 248939, at *4-6 (S.D.N.Y. Jan. 16, 2020) (interpreting a merger clause that provided that, in the event two agreements contained conflicting terms, the more recent agreement would govern).

The merger clause of the 2017 Agreement provides that the two agreements reflect the entirety of the parties' agreements and precludes extrinsic proof about their terms. The parties could have drafted a provision that, for example, incorporated non-conflicting provisions of the 2015 Agreement, but they elected not to do so. If the merger clause were construed as broadly as Amgen urges, the 2017 Agreement's references and express incorporation of individual sections of the 2015 Agreement would be unnecessary. Neither the language of the merger clause, nor the 2017 Agreement read in its entirety, reflect that the parties intended the merger clause to incorporate the entirety of the 2015 Agreement.

Amgen also urges that the survivability provision of Amendment No. 2 to the 2015 Agreement reflects the parties' intent to incorporate section 7.2 into the 2017 Agreement. Pursuant to Amendment No. 2 to the 2015 Agreement, section 7.2 survives termination of the 2015 Agreement only as to a "Distracting Program" that involves a CGRP inhibitor like Aimovig. (Amendment No. 2 § 2.55.) Because the 2017 Agreement relates only to the commercialization of Aimovig in the United States, Amgen urges that by limiting the provision's survivability to CGRP-related products, the parties conformed section 7.2 to the 2017 Agreement, and altered its "substantive nature and scope." (Opp. Mem. 20 n. 94.)

But agreeing that a narrowed portion of section 7.2 will survive through the term of the 2017 Agreement does not make section 7.2 a part of the 2017 Agreement. If Novartis has breached the 2015 Agreement by engaging in a "Distracting Program," thereby permitting Amgen to terminate the 2015 Agreement, the fact that section 7.2 survives and remains enforceable does not make it a part of the 2017 Agreement. As originally drafted, the 2015 Agreement listed numerous provisions that would survive termination of the 2015 Agreement. (2015 Agrmt. § 15.4.) If, post-termination, one of those provisions were breached, the parties were to enforce their rights and obligations under the 2015 Agreement. The parties easily could have included language allowing for termination of the 2017 Agreement based on a breach of section 7.2 of the 2015 Agreement. They elected not to do so.

The contracts at issue were negotiated at arm's length by well-resourced parties represented by sophisticated counsel. The text of the 2017 Agreement reflects their familiarity with the intricacies of the 2015 Agreement. The parties could have drafted a "Distracting Program" provision specifically for the 2017 Agreement or incorporated section 7.2 by reference, as they did with many other provisions of the 2015 Agreement. They elected not to do so. Amgen's interpretation requires a strained reading of the contracts, one that is not supported by their express terms.

The Court concludes that the 2017 Agreement does not incorporate the "Distracting Program" provision of section 7.2 of the 2015 Agreement. Accordingly, the Court concludes that Novartis is entitled to a declaration that it did not breach the 2017 Agreement based on the Sandoz-Alder CMA.

II. Amgen's Motion for Judgment on the Pleadings on Count I Is Denied.

Count I of the Complaint seeks a declaration that Novartis did not breach the 2015 Agreement when Sandoz entered into the CMA with Alder, and that therefore "there is no basis [for Amgen] to terminate the 2015 Agreement." (Compl't ¶¶ 72-77.) For reasons that will be explained, Amgen's motion to dismiss Count I will be denied.

The Court accepts as true the facts set forth in Novartis's pleadings. As discussed, section 7.2 states that "neither Party shall, itself or through its Affiliates, directly or indirectly conduct or participate in, or advise, assist or enable a Third Party to conduct or participate in, any Distracting Program." The Complaint alleges that Sandoz and Novartis share a common indirect parent, and that Sandoz entered into the CMA with Alder for the manufacture of eptinezumab. (Compl't ¶¶ 23-24.) In its answer to Amgen's counterclaims, Novartis admits upon information and belief that eptinezumab is a CGRP inhibitor. (Novartis Answer ¶ 53.) Further, while the parties initially excluded Sandoz from the definition of an "Affiliate," Amendment No. 2 deleted that language from the 2015 Agreement, meaning that, on the effective date of Amendment No. 2, Sandoz became an "Affiliate" of Novartis. (2015 Agrmt. § 1.2; Amendment No. 2 § 2.6.) Amgen urges that, based on the foregoing, the pleadings establish that Novartis, through its Sandoz "Affiliate," has assisted a third party in the conduct of a "Distracting Program," thereby breaching section 7.2 of the 2015 Agreement.

Novartis raises two arguments in opposition. First, it urges that because the Sandoz-Alder CMA predates the 2015 Agreement, the CMA is outside the scope of section 7.2. It is undisputed that Sandoz entered into the CMA with Alder on or about May 4, 2015. The 2015 Agreement has an effective date of August 28, 2015. The representations, warranties and covenants set forth at article 12 of the 2015 Agreement make no mention of the parties' then-

existing participation in a "Distracting Program." Therefore, Novartis urges, because Sandoz entered into the CMA before the 2015 Agreement came into effect, it falls outside the parties' agreement that they "shall" not participate in a Distracting Program.

But the plain language of section 7.2 is broader than the interpretation urged by Novartis. It provides that "neither Party shall, itself or through its Affiliates" participate in a third party's "Distracting Program" and does not merely provide that the parties would refrain from commencing a new "Distracting Program." It is undisputed that, once Amendment No. 2 went into effect, Sandoz became an "Affiliate" of Novartis, and that the CMA relates to the manufacture of a CGRP inhibitor. Sandoz's entry into the CMA may pre-date its status as an "Affiliate," but the pleadings reflect that its participation in the manufacture of eptinezumab continued after Amendment No. 2 went into effect. If the parties had intended to limit section 7.2 only to participation in a newly initiated "Distracting Program," they could have said so in the Agreement.

Separately, Novartis urges that under section 7.2 a breach occurs only where "Affiliates" participate in a Distracting Program at the direction or instruction of a party – that is, instances where Novartis or Amgen have acted "through" an affiliate. The Complaint alleges that Sandoz entered into the CMA on its own accord, without direction or instruction from Novartis, and that Sandoz and Novartis are mere "sister" companies, and not direct or indirect subsidiaries of one another. (Compl't ¶ 41.) In Novartis's view, there has been no breach of section 7.2 because Sandoz, an Affiliate, did not participate in in a Distracting Program at its instruction or on its behalf.

Section 7.2 provides that "neither Party shall, itself or through its Affiliates, directly or indirectly conduct or participate in, or advise, assist or enable" another's Distracting

Program. Giving the words their plain meaning in context, it is a restriction on a "Party" and makes it clear that the "Party" may not evade the restriction by acting "through" Affiliates. If it had been intended as a blanket restriction on both the Party and its Affiliates, it could easily have been written to convey that meaning, for example, with the words: "neither Party nor its Affiliates shall. . . ." A proper construction should take account that the subject of the sentence is "Party," and not "Affiliates," and give meaning to the word "through."

The Court construes the language to require some involvement by the party in an affiliate's participation in a "Distracting Program." For liability to attach for actions by an Affiliate, the Affiliate's involvement need not be at the instruction or direction of a party, but some affirmative act by the party must have been performed "through its Affiliates, directly or indirectly . . . ." If the parties had intended a blanket prohibition against any affiliate's participation in a "Distracting Program," section 7.2 could have provided that "neither the Parties nor their Affiliates" would participate in a "Distracting Program."

There is no serious dispute that Novartis and Sandoz share a common parent company or that eptinezumab is a CGRP inhibitor. To prevail, Amgen must prove that Novartis has acted "through" its Sandoz affiliate by "participat[ing] in, or advis[ing], assist[ing] or enabl[ing]" an eptinezumab program. The parties are free to conduct discovery on the subject.

Amgen's motion will therefore be denied as to Count I.

III. Amgen's Motion for Judgment on the Pleadings on Count IV Is Denied.

Count IV seeks a declaration that Novartis has cured any breach related to the Sandoz-Alder CMA because Sandoz and Alder have entered into an agreement for the CMA's termination. (Compl't ¶¶ 91-96.) Novartis seeks a declaration that, because any breach has been cured, Amgen does not have a contractual basis to terminate either agreement. (Compl't ¶ 96.)

Amgen moves under Rule 12(c) to dismiss Count IV. For the reasons explained, the Court has concluded that Novartis has demonstrated its entitlement to a declaration that it did not breach the 2017 Agreement. The issue of cure is therefore moot as to the 2017 Agreement, and the Court discusses Count IV only as it pertains to the claimed breach of the 2015 Agreement.

In the event that one party asserts that the other is in "material breach," the 2015 Agreement grants "the breaching Party (or its Affiliate)" a 60-day period to cure the breach. (2015 Agrmt. § 15.2.2.) If the claimed breach is not cured, the party asserting breach may then terminate the agreement. (Id.) If the purported breaching party asserts a good-faith basis for disputing the termination, the Agreement remains in effect, pending adjudication by a state or federal court in New York, applying New York law. (Id. & § 16.3.)

The Complaint alleges that on January 1, 2019, while the cure period was in effect, Sandoz and Alder entered into an agreement to terminate the CMA (the "Termination Agreement.") (Compl't ¶ 56.) As summarized in the Complaint, Sandoz is required to continue manufacturing eptinezumab for an additional three to five years, "with significant financial incentives available to Alder if it ends the relationship sooner." (Compl't ¶ 57.) Novartis alleges that because Sandoz and Alder have agreed to terminate the CMA, "any alleged breach of the 2015 and 2017 Agreements has been effectively cured." (Compl't ¶ 58.) It alleges that the termination of the CMA "necessitates a complex technology transfer that spans an extended period" and may take years to complete. (Compl't ¶ 57.) Novartis also alleges that it has firewalls that prevent unauthorized personnel from accessing information about Aimovig. (Compl't ¶ 53.)

Whether the Termination Agreement amounts to a cure under section 15.2.2 of the 2015 Agreement cannot be decided on the pleadings. The 2015 Agreement does not define the term "cure" and does not prescribe any specific conduct to cure a breach of section 7.2. For example, it does not require that a party participating in a "Distracting Program" terminate or divest from the program, even though it prescribes such actions for a party that participates in a "Distracting Transaction." (2015 Agrm't § 7.4.) The Court cannot determine, based on the pleadings, whether the ongoing manufacture of eptinezumab during a multi-year "complex technology transfer" amounts to a cure or a continuation of any breach, and the importance, if any, of Novartis's claimed firewalls about Aimovig. (Compl't ¶¶ 57, 53.)

It would also be premature to adjudicate Count IV because there are threshold questions as to whether Novartis breached the 2015 Agreement, and whether any such breach was material. Section 15.2.2 provides that the agreement may be terminated in the event that there is a material breach, and a party "fails to cure such material breach . . . ." The phrase "material breach" is not defined, and it appears to have been used only in section 15.2.2. Count III of the Complaint seeks a declaration that any breach by Novartis was not "material" and therefore does not provide Amgen with a basis to terminate either agreement. (Compl't ¶¶ 84-90.) It would be premature to decide whether Novartis has cured any purported breach, absent a determination that a breach has occurred and that it was material.

Amgen's motion will therefore be denied as to Count IV.

CONCLUSION.

Novartis's Rule 12(c) motion is GRANTED as to Count II of the Complaint. Amgen's Rule 12(c) motion is DENIED as to Count I and Count IV. The Clerk is directed to terminate the motions and the related letter-motion. (Docket # 44, 47, 52.)

SO ORDERED.

P. Kevin Castel
United States District Judge

Dated: New York, New York
June 9, 2020